

EXHIBIT 6

1 UNITED STATES OF AMERICA
2 SOUTHERN DISTRICT OF ILLINOIS

3 IN RE DEPAKOTE:)
4)
5 STACY BARTOLINI, individually)
6 and as parent and next friend)
7 of H.B., a minor,)
8)
9 Plaintiff(s),)
10)
11 v.) Case No. 3:17-cv-1146-SMY
12)
13 ABBOTT LABORATORIES, INC.,) Lead Case 3:12-cv-52-NJR
14)
15 Defendant.)

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TRANSCRIPT OF FINAL PRETRIAL CONFERENCE

BEFORE THE HONORABLE STACI M. YANDLE
UNITED STATES DISTRICT JUDGE

November 15, 2017

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11/15/2017 - FPTC - Page 1

1 matters.

2 I believe --

3 MR. WILLIAMS: Can I cut through on that, Your
4 Honor?

5 THE COURT: You may.

6 MR. WILLIAMS: I interrupted you and I apologize.

7 THE COURT: Okay.

8 MR. WILLIAMS: As I understood, their objection
9 was to his Top Three testimony --

10 THE COURT: That was one.

11 MR. WILLIAMS: Okay.

12 THE COURT: They have a few bases, and that's what
13 I was trying to get through.

14 MR. WILLIAMS: I'm sorry. Well, I may have -- but
15 if -- he's not a regulatory expert. He's not going to be
16 testifying about labeling or -- so --

17 THE COURT: Right. But I think the issue is, the
18 issue is, and I think it, it -- for me, I think
19 plaintiffs' response raises the issue as well, is that the
20 Top Three is a separate one. We're going to address that.

21 But let me make sure I get here so I can -- the
22 concern that I have, understanding that it's already been
23 subject to previous rulings, and I happen to agree with
24 Judge Rosenstengel's rulings as to the fact that he is not
25 a labeling expert and cannot give warning, that type of --

11/15/2017 - FPTC - Page 29

1 importance of it, significance of it, as to how it
2 accurately, you know, communicates risk, whatever. He can
3 testify to that. But what he cannot testify to, is give
4 an opinion that the labeling or the Dear Doctor Letter was
5 inadequate because it didn't include this information.

6 Now, I know it's a fine line. It's a fine -- I
7 think it's a -- it sounds like it's splitting hairs. He
8 can certainly point out that information is not in there,
9 he just can't render the opinion. Because I believe Dr.
10 Kessler -- you have other labeling experts that are going
11 to go there. But I think what's important and what the --
12 and the crux of the defendants' motion is to make sure
13 that by getting into the details, the plaintiffs are not
14 able to somehow transform Dr. Oakley into a labeling or
15 warning expert.

16 And so, again, my ruling would be consistent to
17 what I believe Judge Rosenstengel has done in the past. I
18 agree with the, with the limitation. And that is, he can
19 certainly give opinions as to, you know, I believe -- that
20 his opinion, that in his experience, valproic acid should
21 not be used by women of reproductive age unless there is
22 no other drug or drug combination that can control her
23 epilepsy, such use should be rare. That opinion and any
24 opinion stemming from that, and --

25 MR. WILLIAMS: Those are appropriate, you're
11/15/2017 - FPTC - Page 34

1 that line being drawn that way, I think that Your Honor
2 has the appropriate rulings.

3 THE COURT: So this is, this is where we're going
4 to deal with this, and I think it's pretty clear. I'm
5 pretty clear on at least where, what my ruling is, and how
6 I believe that ruling fits with what the anticipated
7 testimony is.

8 So, I think we can cut to the chase and I will
9 just say, Mr. Williams, like I said, everything that you
10 said -- that you communicated to the Court that Dr. Oakley
11 was going to testify to, up to the point where you said
12 he's also going to testify to what doctors should have
13 been told? That is nothing but a warnings opinion. And I
14 think that, again, it's pretty clear that Dr. Oakley is
15 not and cannot be transformed into a labeling or a
16 warnings expert. And so again, to the extent that he
17 renders or gives opinions that deal with the, the risks
18 associated with the drug, and he wants to educate the jury
19 on how dangerous the drug is, et cetera, et cetera, et
20 cetera, which I think has been the demarcation in previous
21 trials, that will be allowed. He's allowed to do that.

22 He will not be allowed to talk about what Abbott
23 -- what should have been in Abbott's label or in the Dear
24 Doctor Letter.

25 MR. WILLIAMS: Okay. We're -- if I may, Your
 11/15/2017 - FPTC - Page 38

1 5. What is the rate of disease after
2 exposure?

3 THE REPORTER: Excuse me.

4 MR. WILLIAMS: I'm prone to do that. Thank you.

5 And 6. How many children have been affected?

6 And so you -- that gives you a little bit of, of
7 what he thinks are important guidelines. And he goes
8 through in that supplemental report then how he comes to
9 his conclusions and all.

10 THE COURT: This is, this is, this is still the
11 question for me, Mr. Williams. The only relevance to that
12 particular opinion that Depakote is one of the Top Three
13 -- the only relevance to that particular opinion is,
14 again, to give some context and background to the jury so
15 that they could understand the dangerousness or the
16 devastating effects associated with that drug, which he's
17 going to testify to.

18 The problem is, is that in your briefings you
19 indicate that the basis for that opinion that he intends
20 to give is, is actually the rate at which Depakote causes
21 birth defects and the severity. In other words, he's
22 saying it's one of the Top Three based on the rate of
23 which it causes birth defects and the severity of the
24 birth defects that it causes.

25 I have no problems with his testimony being that
11/15/2017 - FPTC - Page 82

1 it's -- that it's dangerous and the devastating effects
2 and him communicate -- I think he can communicate that to
3 the jury, again, by evidence which you are calling the
4 basis. In other words, to give testimony and to explain
5 to the jury the rate of, at which Depakote causes birth
6 defects, and to give them information or testify as to the
7 severity of some of those effects.

8 The problem comes in, is when he gives an opinion
9 that says it's one of the Top Three most dangerous drugs
10 from this standpoint, without any scientific basis for it,
11 when it's just simply based on his experience -- and I'm
12 saying he's qualified, he's got the experience -- but it's
13 a subjective opinion. So it's a qualitative -- it appears
14 to be a qualitative opinion, but it's actually on a
15 quantitative basis.

16 Because you're, you're saying it's one of the Top
17 Three dangerous drugs based on a comparison. That then
18 puts the -- that opens the door then for the defendants to
19 put on evidence as to the, the similarities or, or what's
20 not similar about these other three drugs that he's
21 referencing. And then we get into a trial within a trial
22 based on what's the most dangerous drugs.

23 To me, that -- my problem is, I believe the
24 effects of that evidence would be much more prejudicial
25 than it is probative, because the only probative value is,

11/15/2017 - FPTC - Page 83

1 again, as background for how devastating the effects of
2 the drug is. Which, because of his experience and his
3 expertise, he's in a position to give the jury a lot of
4 different -- I mean, information -- he can communicate
5 that to them in so many different ways that it's not --
6 that doesn't run into this issue.

7 I, I actually think -- and that's my problem with
8 it. I know Judge Rosenstengel in the past has ruled that
9 it's a qualitative and not a quantitative opinion. I
10 happen to disagree. I think anytime that you, you rank
11 something and you give a ranking to it, you gotta have
12 some type of medical or scientific evidence to, to back
13 that up. It can't be just based on your subjective
14 opinions, based on your expertise and your experience. So
15 I think it's kind of -- that's what makes it misleading.

16 MR. WILLIAMS: Well, if I may, Your Honor, and
17 again, I would direct you to Tab 4-B, his August 31, 2017,
18 report. And it goes through his process for determining
19 that.

20 THE COURT: Okay.

21 MR. WILLIAMS: And as -- I don't know if the
22 Court's had a chance to read that. But if you -- when you
23 do, you'll see that there are really accepted amongst
24 teratologists that there's at least 20 -- about -- around
25 -- approximately 20 human teratogens. I'm not talking

11/15/2017 - FPTC - Page 84

1 situation.

2 All the anti-epileptic drugs we commonly refer to
3 as AEDs, apparently all of them have some teratogenic
4 effect. Okay? And Abbott tries to say, based on prior
5 experience, that all of these drugs are the same and that
6 they all cause problems.

7 And what we want to show is, not only is it the
8 worst AED -- and we'll show evidence from them where it's
9 four times worse than the other AEDs -- not only is that
10 true but it's many, many times worse, and it gets up in
11 the category of the three worst drugs on the market.

12 If the Court -- and I hope the Court will allow us
13 to show that, you know, how the other manufacturers --
14 looking at the conduct of other manufacturers in this
15 situation, in Thalidomide and Accutane, manufacturers have
16 what's called an "I pledge" program and a Steps program.
17 So -- and I had a daughter who took Accutane. And what
18 the manufacturers do in this situation, Your Honor, it's
19 like, if you want to go on Accutane for acne, you have to
20 get a blood test to make sure you are not pregnant; you
21 have to come back a couple weeks later, get another blood
22 test; and then you have to pledge that "I will not" -- "I
23 will be on birth control and I will not be pregnant while
24 I take this drug." And then, and then every time you want
25 to get it refilled, you have to call in and pledge orally

11/15/2017 - FPTC - Page 88